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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,761	05/23/2001	Sharron Gaynor Penn	AEOMICA_X_1	6802

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EXAMINER	
LY, CHEYNE D	

ART UNIT	PAPER NUMBER
1631	19

DATE MAILED: 11/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/864,761	PENN ET AL.	
	Examiner	Art Unit	
	Cheyne D Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *110-130* is/are pending in the application.

4a) Of the above claim(s) *118,119 and 127-130* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *110-117 and 120-126* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *110-130* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5, 7, 9* .
4) ☒ Interview Summary (PTO-413) Paper No(s). 18 .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicants' arguments filed July 02, 2003 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. The new title has been accepted.

3. The priority document US 60/207456 has been accepted.

4. Claims 1-109 have been cancelled.

5. Claims 118, 119, and 127-130 have been withdrawn.

6. Claims 110-117 and 120-126 are examined on the merits.

LACK OF UTILITY UNDER 35 U.S.C. § 101:

7. The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

8. Claims 110-117 and 120-126 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

9. This rejection is maintained with respect to claims 110-117 and 120-126, as recited in the previous office action mailed April 09, 2003.

Response to Applicant's Arguments

10. Applicants argue by stating that Applicants do not "understand the Examiner to mean that methods of manufacturing demonstrably useful products – nucleic acid microarrays – lack utility, Applicants believe that the rejection is not addressed to the invention as presently claimed." Applicants' argument has been fully considered and found to be unpersuasive due to the claimed invention is directed to the critical limitation of SEQ ID NO. 17240. As discussed in the previous Office Action, mailed April 09, 2003, and re-iterated below, the claimed invention lacks utility under 35 U.S.C. §101 because the critical limitation of said invention is not supported by a specific and substantial utility. Therefore, the claimed

invention lacks utility under 35 U.S.C. §101 when the critical limitation (SEQ ID NO. 17240) of said invention is not supported by a specific and substantial utility.

11. It is re-iterated the claimed subject matter is not supported by a specific, substantial, and credible utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

12. The critical limitation of the method of manufacturing the microarray in claims 110-117 and 120-124 containing a broad class of single exon probes. More specifically, the critical limitation of the method of manufacturing the microarray of claims 125 and 126 is the microarray containing single exon probes comprising nucleotide sequence SEQ ID NO: 17240. While some data are supplied for several sequences, such as for AP000217-1 and AP000047-1 on page 255, Table 2, no data or reasoning therein indicate any specificity regarding the elected SEQ ID NO: 17240. It is acknowledged that Applicants disclose the microarray containing the class of single exon probes has a utility for gene expression analysis. However, the intended utility is applicable to nucleic acids in general and not particular or specific to the polynucleotide being claimed.

13. Further, the claimed polynucleotide is not supported by a substantial utility because no substantial utility has been established for the claimed subject matter. For example, a nucleic acid may be utilized to obtain a protein. The protein could then be used in conducting

research to functionally characterize the protein. A starting material that can only be used to produce a final product does not have substantial asserted utility in those instances where the final product is not supported by a specific and substantial utility. In this case, the protein produced as a final product resulting from processes involving the nucleic acid does not have asserted or identified specific and substantial utilities. Identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved does not define a "real world" context for use. Similarly, the other listed utilities and asserted utilities as summarized above or in the instant specification are neither substantial nor specific due to being generic in nature and applicable to many such compounds.

14. Applicants disclose "the probe sequences was BLASTed against the human EST data set, the NR data set, and SwissProt GenBank (May 7, 1999 release 2.0.9)" and protein similarity analysis was performed to predict the functional features of the sequences (Page 246, lines 31-33 to page 247, lines 1-17; also Table 1).

15. It is noted that applicant has identified a sequence, which is known in the prior art and which has a stated sequence similarity to the claimed sequence such as those listed in Table 1. Absent factual evidence, one skilled in the art would have reason to doubt that sequence similarity alone would reasonably support the assertion that the biological activity of the claimed subject matter would be the same as that of the similar sequence. Furthermore, it is unclear whether the similar sequence identified in the prior art has actually been tested for the biological activity or whether this also is an asserted biological activity based upon sequence similarity to yet a different sequence. Note that it would have been well known in the art that sequence similarity does not reliably correlate to structural similarity and that

structural similarity does not reliably result in similar or identical biological activities. For example, it would have been well known that even a single nucleotide or amino acid change or mutation could destroy the function of the biomolecule in many instances, albeit not in all cases. In the absence of factual evidence characterizing the structural and functional components of the biomolecule, the effects of these changes are largely unpredictable as to which ones will have a significant effect and which ones will be silent mutations having no effect. Several publications document the unpredictability of the relationship between sequence, structure, and function, although it is acknowledged that certain specific sequences have been found to be conserved in biomolecules having related function following a significant amount of further research. See Lopez et al. (Molecular Biology, 32:881-891,1999); Attwood (Science, 290:471-473, 2000); Gerhold et al. (BioEssays, 18(12):973-981, 1996); Wells et al. (Journal of Leukocyte Biology, 61(5):545-550, 1997); and Russell et al. (Journal of Molecular Biology, 244:332-350, 1994). However, this level of factual evidence is absent here.

LACK OF ENABLEMENT UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

16. Claims 110-117 and 120-126 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention without undue experimentation.

17. This rejection is maintained with respect to claims 110-117 and 120-126, as recited in the previous office action mailed April 09, 2003.

Response to Applicant's Arguments

18. Applicants' argument to overcome the instant 35 U.S.C. § 112, First Paragraph, rejection has been fully considered and found to be unpersuasive. The response to Applicants' argument to overcome the 35 U.S.C. §101 rejection above has been extended to Applicants' argument for the instant 35 U.S.C. § 112, First Paragraph rejection.

19. Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

20. The claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above (refer to 35 U.S.C. § 101 rejection), one skilled in the art would not know how to use the claimed invention without undue experimentation.

21. Further, Applicants disclose "identification of functional genes from genomic data remains, however, an imperfect art" (Page 7, lines 14-15). The method of this instant

application relies nucleic acid and protein similarity analysis for predicting the functional features of the sequences as cited above. Therefore, for a method that relies on unpredictable art, one skilled in the art would not know how to predictably use the claimed invention without undue experimentation.

CONCLUSION

22. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

23. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

24. This application contains claims 118, 119, and 127-130 drawn to an invention nonelected with traverse in Paper No. 13, filed March 07, 2003. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

25. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center

located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 193), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is (703) 872-9306.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

28. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
11/3/03

ARDIN H. MARSCHEL
PRIMARY EXAMINER